Abbott

IDENTIFY COVID-19 CONTAGIOUS PATIENTS **IN 15 MINUTES**

With Patient-friendly Nasal Sample Collection

PANBIO™ COVID-19 Ag RAPID TEST DEVICE

FOR PEOPLE SUSPECTED OF **COVID-19 EXPOSURE**

HIGH PERFORMANCE COMPARED TO NASAL PCR

- Panbio™ vs. Nasal PCR: Sensitivity 98.1%, Specificity 99.8%

PATIENT-FRIENDLY NASAL SAMPLE COLLECTION

- ~ 2 cm insertion depth minimizes undesirable reflexes like coughing or sneezing[1]

FAST IDENTIFICATION OF CONTAGIOUS INDIVIDUALS

- Test results in 15 minutes

ACCESSIBLE, LARGE-SCALE TESTING HELPS CONTAIN THE VIRUS SPREAD

- Enables immediate treatment or isolation measures to minimize transmission

HIGH PERFORMANCE
COMPARED TO NASAL PCR

		NASAL PCR TEST RESULT		
		POSITIVE	**NEGATIVE**	**TOTAL**
PANBIO™ COVID-19 Ag TEST RESULT	**POSITIVE**	102	1	103
	NEGATIVE	2	403	405
	TOTAL	104	404	508

SENSITIVITY	**SPECIFICITY**	**OPA**
98.1% [93.2%; 99.8%]	**99.8%** [98.6%; 100.0%]	**99.4%** [98.3%; 99.9%]

Performance data was calculated from a study of individuals suspected of exposure to COVID-19 or who have presented with symptoms in the last 7 days.

The clinical performance data was also calculated vs nasopharyngeal swab specimens using an FDA EUA RT-PCR reference and has a sensitivity of 91.1% (95% CI: 84.2-95.6%) and specificity of 99.7% (95% CI: 98.6-100.0%).

Positive agreement is higher with samples of Ct values ≤33 with a sensitivity of 99.0%. Patients with Ct value >33 are no longer contagious.[2]

PCR = polymerase chain reaction
OPA = overall percent agreement

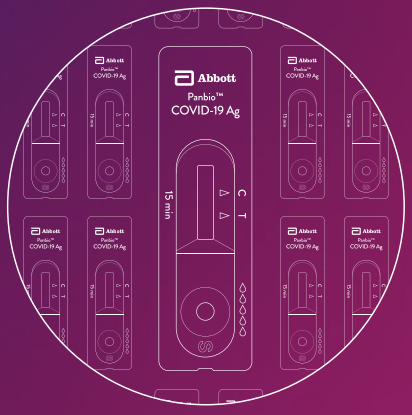
PATIENT-FRIENDLY NASAL SAMPLE COLLECTION **ENABLES SCALE-UP** IN NONTRADITIONAL SETTINGS

~ 2 CM NASAL SWAB INSERTION DEPTH

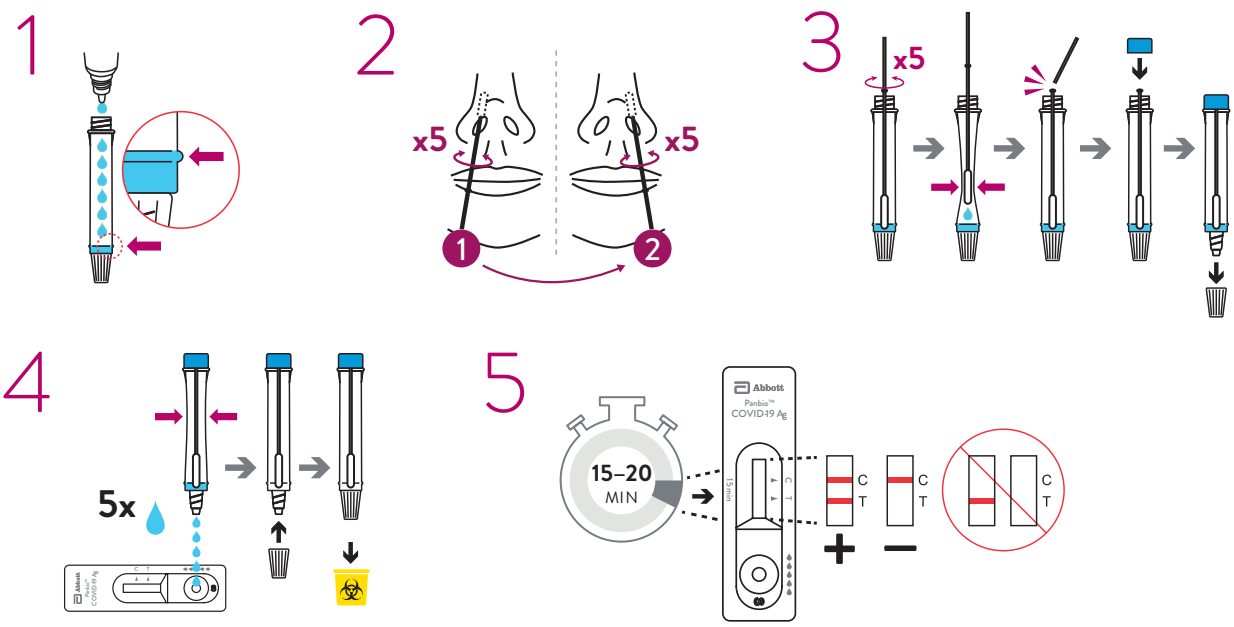
- Minimize undesirable reflexes like coughing or sneezing[1]
- Reduce risk of infecting healthcare workers by reducing the duration of the procedure[3]
- Less invasive and less patient discomfort[3] helps overcome patient resistance to procedure
- Lower technical complexity[3]; easier training for staff

LARGE SCALE DEPLOYMENT AT THE POINT OF CARE

- Mass production and deployment capability
- Can be used in a wide variety of non-laboratory settings
- Run multiple tests in parallel for high throughput
- No special/additional instruments required



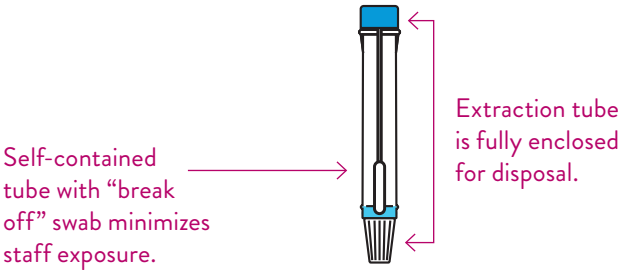
SIMPLE TEST PROCEDURE



Consult Instructions for Use for complete procedure.

BIOHAZARD RISK-REDUCTION FEATURES

Reduce the risk of facility contamination and healthcare worker exposure.



SPECIFICATIONS

- **TEST TIME:** 15 MINUTES
- **STORAGE:** 2°C–30°C
- **CE MARK, WHO EUL**
- **SAMPLE TYPE:** NASAL SWAB

INTENDED USE: Panbio™ COVID-19 Ag Rapid Test Device is an *in vitro* diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasal swab specimens from individuals who meet COVID-19 clinical and/or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation. The test provides preliminary test results. Negative results don’t preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2.

ORDER INFORMATION

PANBIO™ COVID-19 Ag RAPID TEST DEVICE (NASAL)

CATALOG NUMBER:	41FK11 (CE, WHO EUL)
CONTENTS:	• 25 Test Devices • 1 Buffer (9 mL/bottle) • 25 Extraction Tubes • 25 Extraction Tube Caps • 1 Positive Control Swab • 1 Negative Control Swab • 25 Sterilized Nasal Swabs for Sample Collection • 1 Tube Rack • 1 Quick Reference Guide • 1 Instructions for Use